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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,306	09/15/2000	Zhong Zhong	ORT1296	2391
7590 02/09/2004				
Ralph Palo One Johnson and Johnson Plaza New Brunswick, NJ 08933-7003			EXAMINER CARLSON, KAREN C	
			ART UNIT 1653	PAPER NUMBER

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/663,306	Applicant(s) ZHONG ET AL.	
	Examiner Karen Cochrane Carlson, Ph.D.	Art Unit 1653	

-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) 1-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 82-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10/03</u> . | 6) <input type="checkbox"/> Other: |

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on November 6, 2003 has been entered.

This Office Action is in response to the paper filed November 6, 2003. Claims 1-85 are currently pending. Claims 1-81 are withdrawn from further consideration by the Examiner because these Claims are drawn to non-elected inventions. Claims 82-85 are currently under examination.

Maintenance of Notations, Objections and Rejections

Note again to Applicants: The IDS filed January 29, 2001 (Paper 34) states that there are 3 sheets of references cited—see top wherein the statement "Sheet 1 of 3" is found. However, sheets 2 and 3 are not found in the application, and sheet 1 appears to list all of the submitted references.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 82-85 are again rejected under 35 U.S.C. 102(b) as being anticipated by Mazer et al. (USP 5,698,222; issued December 6, 1997). Mazer et al. teach a calcium supplement (Claims 82, 84) in a pharmaceutical formulation (Claims 83, 85).

Claims 82 and 84 are drawn to compounds that modulate the response to extracellular modulators, formally referred to as compounds, that activate protease to cleave a membrane bound constitutively active transcription.

At page 17-18 of the specification, a fusion protein comprising of a strong transcription activator and a dominant membrane localization sequence comprising a protease cleavage site is cleaved by the protease calpain, which cleaves the fusion protein and releases the strong transcriptional activator from the membrane to activate protein expression. Calpain activity is stated to be strictly dependent on calcium. Therefore, calcium is a compound that stimulates the activity of a protease to release a transcription factor from the membrane.

Applicants again argue that each and every element of the claim must be either expressly or inherently present in a single art prior reference to be anticipated by the reference. Applicants assert that because Mazer et al. do not teach that their calcium supplement will activate a protease that will cleave a protease cleavage site found in a membrane-bound transcription factor, this calcium supplement cannot anticipate the claims. Applicants urge that it is well-known that the release of intracellular calcium and intracellular calcium concentrations is not a function of extracellular calcium. Applicants invite the examiner to provide a reference for the record that extracellular calcium supplements increase intracellular calcium concentrations in a manner that necessarily stimulates the activity of intracellular protease. The

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Examiner does not understand the request. Where else does intracellular calcium originate from if not from an outside source? The claimed compound has nothing to do with stimulating the release of intracellular calcium stores. The claimed compound is a compound that stimulates the activity of a protease. Applicants themselves teach in the specification that protease is stimulated by calcium.

A patent will not be granted on a known compound, whether this known compound has been identified in a different manner or used in a different manner from that taught in the prior art. There is sufficient evidence that the product disclosed by the reference is Applicants' product, and the burden is shifted to Applicants to distinguish the two. See *In re Best*, 195 USPQ 430 and *Ex Parte Gray* 10 USPQ 2d 1922, 1923. Therefore, this argument is not persuasive.

New Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 82-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 82-85 have been amended to refer to a compound that modulates the response to an extracellular ligand, when in fact that compound acts downstream from any extracellular receptor activation at the transcriptional level. Thus, there is not nexus between the implied activity of modulating the response of an extracellular ligand and the actual activity of the compound which is to stimulate protease activity to release a membrane bound transcription factor from a membrane.

It is not clear what the term "modulates" means. Is the response to the extracellular ligand increased or decreased? How would one know? Extracellular ligands are known to

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increase the expression of some proteins, and decrease the expression of others; how would one know if the compound which stimulates protease activity also results in altered gene expression?

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in cursive script that reads "Karen Cochrane Carlson". The signature is written in dark ink and is positioned above the printed name and title.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER